IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

HAROLD E. CUTLER

Serial No.: 10/593,172

Filed: September 15, 2006

For: ORAL DEVICE

Attorney Docket No.: CUTL 0101 PUSA (formerly 065391-0002)

Group Art Unit: 3771

Examiner: Colin W. Stuart

**DECLARATION OF HAROLD E. CUTLER**
**UNDER 37 C.F.R. § 1.132**

Mail Stop RCE
Commissioner for Patents
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Harold Cutler, do hereby declare and state as follows:

During the 1990's, sleep apnea devices employing a soft palate lifter were adjudged to be ineffective and ceased to be an accepted method of treatment. Applicant is of the opinion the failure in performance of soft palatial lifters was due to deficiencies in design rather than a lack of validity in the concept of addressing collapse of the soft palatial tissue directly with a soft palate lifter.

The design presented in the instant application overcomes the deficiencies inherent in the earlier design(s), and in fact, the resultant synergistic effect of coupling a soft palate lifter, as designed, and a tongue retainer as presented in the instant application produces favorable test results far beyond what would be expected by one of average skill in the art.

Applicant understands that it is accepted practice to include comparative test results along with those of the subject device, however, there is no similar device and hence no comparable test

results available for applicant to include, and if there were, such test results are proprietary and would not be made available to support a competing product.

The test results themselves are significant enough to stand on their own in view of the fact that this type of device is out of favor due to a lack of confidence in their effectiveness within the industry.

I direct your attention to two tests performed at the Center for Sleep Medicine, a sleep apnea testing facility accredited by the American Academy of Sleep Medicine. A nocturnal polysomnogram was performed with continuous monitoring of the central and occipital electroencephalographic (EEG) derivations, the electrooculogram (EOG), the electromyogram (EMG) from the muscles beneath the chin and the right and left anterior tibialis muscles, arterial blood oxygen saturation and pulse rate, nasal/oral respiratory airflow, thoracic and abdominal respiratory movements, snoring, body position, and the electrocardiogram. Both tests were performed on different dates at the Grayslake, Illinois Center for Sleep Medicine testing facility. The first test established the baseline data without the use of the device, and the second measuring the changes produced while wearing the device. Test data is collected when brain wave patterns indicate that the subject is in a stage of sleep.

A number of readings from different sources were recorded, but Dr. Levy, a Board certified Sleep Medicine Specialist in charge of interpreting the results, has placed his emphasis on three main factors, the Apnea/Hypopnea Index, the Blood/O2 Saturation, and Sleep Efficiency (the percentage of time in bed asleep).

In determining the effectiveness of the device as determined by the tests, the following criteria are recognized:

A hypopnea is defined as a cessation of breathing for at least 10 seconds accompanied by a drop in Blood/O2 saturation of 2% or more.

Under 5 hypopneas per hour are considered NORMAL.

From 5-15 hypopneas per hour are considered MILD SLEEP APNEA.

From 15-30 hypopneas per hour are considered MODERATE SLEEP APNEA.

Over 30 hypopneas per hour are considered SEVERE SLEEP APNEA.

Blood/O2 saturation above 90% is considered NORMAL.

Sleep Efficiency of 80% plus is considered NORMAL

BASELINE TEST- PAGE 1

The Center for Sleep Medicine
CUTLER,HAROLD
Study Date: 2/3/2007

**GRAYSLAKE DIAGNOSTIC SLEEP STUDY REPORT**

**PATIENT NAME:** HAROLD
CUTLER **PSGDATE:** 2/3/2007

**STUDY NUMBER:**070144GL **DOB:** 04/20/49 **SCORER:** ABM

**REFERRING PHYSICIAN:** MONAHAN/ ABM **TECH:** JH

POLYSOMNOGRAPHIC RESULTS

| | | |
|---|---|---|
| Total Bedtime: | **MAKE SURE TRT IS CHECKED!!!** | 424.0 |
| Total Sleep Time: | | 234.5 |
| Sleep Efficiency: | | 55.3 |
| Sleep Latency: | | 12.0 |
| REM Latency: | | 290.0 |
| Stage 1 (percent of total sleep time): | | 57.4 |
| Stage 2 (percent of total sleep time): | | 29.2 |
| Stage 3\4 (percent of total sleep time): | | 0.0 |
| REM (percent of total sleep time): | | 13.4 |
| Baseline SaO2 Awake: | | 93 |
| Baseline SaO2 REM: | | 93 |
| Baseline SaO2 NREM | | 92 |
| Lowest SaO2 Recorded: | | 85 |
| Periodic Limb Movement Index: | | 18.2 |
| Periodic Limb Movment Index with Arousal: | | 3.8 |
| Total Arousal Index: | | 63.5 |
| Mean Heart Rate: | | 74 |
| **Apnea Hypopnea Index:** | | **54.8** Per Hour |
| Total Respiratory Events: | | 214 |
| Central Apneas: | | 3 |
| Mixed Apneas: | | 1 |
| Obstructive Apneas: | | 9 |
| Hypopneas: | | 201 |
| **RERA Index:** | | **0.0** |
| RERA Number: | | 0 |

# BASELINE TEST- PAGE 2

**General Information**

**Name:** CUTLER, HAROLD
**ID:** 070144GL
**Sex:** male
**Age:** 57 [4/20/1949]

**BMI:** 26
**Height:** 71 in
**Weight:** 190 lb
**Date:** 2/3/2007

**Physician:** ABM,
**Technician:** JH,
**Record Number:** X4RTKRRYE3P9U7G
**Scorer:** ABM

**Time in minutes for each oxygen saturation range per stage of sleep**

| | Total | 00% - 59% | 60% - 69% | 70% - 79% | 80% - 89% | 90% - 100% | Minimum O2 Sat. |
|---|---|---|---|---|---|---|---|
| Total | 424.00 | 1.00 | 0.00 | 0.00 | 130.88 | 287.62 | 83% |
| REM | 31.50 | 0.00 | 0.00 | 0.00 | 16.67 | 14.83 | 84% |
| NREM | 203.00 | 0.13 | 0.00 | 0.00 | 88.78 | 114.08 | 86% |
| Wake | 189.50 | 0.85 | 0.00 | 0.00 | 25.43 | 158.72 | 83% |

**Percent time for each oxygen saturation range per stage of sleep**

| | % Total | 00% - 59% | 60%- 69% | 70% - 79% | 80% - 89% | 90% - 100% |
|---|---|---|---|---|---|---|
| Total | 100.00% | 0.23% | 0.00% | 0.00% | 30.87% | 67.8% |
| REM | 7.43% | 0.00% | 0.00% | 0.00% | 3.93% | 3.5% |
| NREM | 47.88% | 0.03% | 0.00% | 0.00% | 20.94% | 26.9% |
| Wake | 44.69% | 0.20% | 0.00% | 0.00% | 6.00% | 37.4% |

**Percent time for each oxygen saturation range per body position**

| | % Total | 00% - 59% | 60% - 69% | 70% - 79% | 80% - 89% | 90% - 100% | Minimum O2 Sat. |
|---|---|---|---|---|---|---|---|
| Total | 100.00% | 0.23% | 0.00% | 0.00% | 30.87% | 67.84% | 83.0% |
| Prone | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | --% |
| Supine | 20.64% | 0.20% | 0.00% | 0.00% | 4.34% | 15.04% | 86.0% |
| Right | 79.36% | 0.03% | 0.00% | 0.00% | 26.53% | 52.80% | 83.0% |
| Left | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | --% |
| Upright | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | --% |

**Number of desaturation events for each oxygen saturation range per stage of sleep**

| | Total | 00% - 59% | 60% - 69% | 70% - 79% | 80% - 89% | 90% - 100% | Baseline/Minimum (Average) |
|---|---|---|---|---|---|---|---|
| Total | 298 | 0 | 0 | 0 | 144 | 154 | 92% / 89% |
| REM | 23 | 0 | 0 | 0 | 13 | 10 | 93% / 89% |
| NREM | 182 | 0 | 0 | 0 | 99 | 83 | 92% / 89% |
| Wake | 93 | 0 | 0 | 0 | 32 | 61 | 93% / 89% |

**Duration ranges in seconds of desaturation events per stage of sleep**

| | Total | 00 - 09 | 10 - 19 | 20 - 29 | 30 - 39 | 40 - 49 | 50 and above |
|---|---|---|---|---|---|---|---|
| Total | 298 | 0 | 100 | 76 | 50 | 26 | 46 |
| REM | 23 | 0 | 3 | 2 | 4 | 2 | 12 |
| NREM | 182 | 0 | 63 | 52 | 30 | 18 | 19 |
| Wake | 93 | 0 | 34 | 22 | 16 | 6 | 15 |

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## SLEEP STUDY REPORT

**PATIENT NAME:** Harold Cutler **DATE OF STUDY:** 03-07-2010

**STUDY NUMBER:** 10-0506-GL **DATE OF BIRTH:** 04-20-1949

**REFERRING PHYSICIAN:** Barry Levy, M.D.

**IDENTIFICATION AND PRESENTING COMPLAINTS:** The study is to evaluate efficacy of an oral appliance invented by Mr. Cutler for treatment of obstructive sleep apnea. No medications are reported. The design of the oral appliance, which elevates the soft palate and depresses the tongue, may prevent PTAF signal from having been recorded.

**RECORDED PARAMETERS:** The patient's nocturnal polysomnogram was a continuous monitoring of the frontal, central, and occipital electroencephalographic (EEG) derivations, the electrooculogram (EOG), the electromyogram (EMG) from the muscles beneath the chin and the right and left anterior tibialis muscles, arterial blood oxygen saturation and pulse rate, nasal/oral respiratory airflow, thoracic and abdominal respiratory movements, snoring, body position, and the electrocardiogram (ECG).

**SLEEP ARCHITECTURE AND CONTINUITY:** Sleep latency was 14 minutes. REM latency was 55 minutes, which is mildly shortened. Sleep efficiency was 80.4 percent. REM quantity was 11.4 percent. There were 320 minutes of sleep recorded out of 398 minutes.

**RESPIRATORY MONITORING:** Intermittent mild to moderate snoring was noted. The apnea/hypopnea index was 9.0 per hour. This is very positional and is seen only supine at 16.4 per hour. The apnea/hypopnea index was normal in side sleep at 3.0 per hour. Saturation remained at or above 90 percent SaO2 throughout the night. The events seen were hypopneas. Some central events were noted (13 of 48 events were central apneas).

**PERIODIC LIMB MOVEMENTS:** Periodic limb movements were frequent at 29.1 per hour with 9.0 per hour associated with arousals.

**EKG:** No arrhythmias were seen.

**IMPRESSION/RECOMMENDATIONS:**

- Mild positional obstructive sleep apnea. The supine apnea/hypopnea index was 16.4 per hour, but it is normal in side sleep at 3.0 per hour. Oxygenation was well maintained throughout the night. Avoidance of the supine sleep position along with the use of the current oral appliance is suggested.
- Periodic limb movements were seen at 29.1 per hour with 9.0 per hour associated with arousal. Treatment is indicated if symptomatic.

TEST WITH DEVICE – PAGE 2

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| DIAGNOSTIC POLYSOMNOGRAM DATA | | | |
|---|---|---|---|
| Lights Out: | 10:29 p.m. | Sleep Efficiency: | 80.4% |
| Lights On: | 05:06 a.m. | Sleep Latency (Min.): | 14.0 |
| Total Bed Time (Min.): | 398.0 | REM Latency (Min.): | 55.0 |
| Total Sleep Time (Min.): | 320.0 | | |
| **PERCENT TOTAL SLEEP TIME:** | | **MINUTES TOTAL SLEEP TIME:** | |
| Stage N1 % of TST: | 41.1 | Minutes Stage N1: | 131.5 |
| Stage N2 % of TST: | 47.3 | Minutes Stage N2: | 151.5 |
| Stage N3 % of TST: | 0.2 | Minutes Stage N3: | 0.5 |
| Stage R % of TST: | 11.4 | Minutes Stage R: | 36.5 |
| **BASELINE SaO2:** | | | |
| Awake: | 95% | PLM Index: | 29.1 |
| REM: | 95% | PLM Index/Arousal: | 9.0 |
| NREM: | 95% | Arousal Index: | 42.6 |
| Lowest SaO2 Asleep: | 90% | Mean Heart Rate Asleep: | 60 |
| | | | |
| **Apnea/Hypopnea Index (per hour):** | 9.0 | **AHI/TIME VALUES:** | |
| Total Respiratory Events: | 48 | **Supine AHI/Minutes of Sleep:** | 16.4/142.5 |
| Central Apneas: | 13 | **Lateral AHI/Minutes of Sleep:** | 3.0/177.5 |
| Mixed Apneas: | 0 | **Prone AHI/Minutes of Sleep:** | N/A |
| Obstructive Apneas: | 0 | **REM AHI/Minutes of Sleep:** | 1.6/36.5 |
| Hypopneas: | 35 | **NREM AHI/Minutes of Sleep:** | 9.9/283.5 |

Thank you very much for the opportunity to participate with you in Mr. Cutler's care. If I may be of any further assistance, please do not hesitate to contact me at The Center for Sleep Medicine.

Barry Levy, M.D.
Board Certified Sleep Medicine Specialist
BL/kc/js

## RESULTS ANALYSIS

THE TEST PERFORMED WITHOUT USING THE DEVICE SHOWED:

There was an average of 54.8 Hypopneas per hour, which is classified as Severe Sleep Apnea. There were 51.1 Hypopneas per hour in the side sleep position which is also classified as Severe.

The Blood/O2 concentration was at, or above, the 90% acceptable level for only 67.8% of the sleep time.

Sleep Efficiency was 55.3%

THE TEST PERFORMED WHILE USING THE DEVICE SHOWED:

There overall Hypopnea Index was 9 per hour classified as Mild Sleep Apnea with 3 Hypopneas per hour in the side sleep position which is considered Normal.

The Blood/O2 concentration was above 90% the entire sleep time averaging 95%, the same Blood/O2 concentration during wake time.

Sleep Efficiency was 80%.

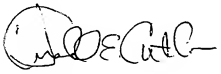
## CONCLUSION

The coupling of a soft palate lifter with a tongue retainer as presented in the immediate application results in a unique oral device capable of reducing the major indices of symptoms of severe sleep apnea to those of mild sleep apnea, and with avoidance of the supine position, to well within normal levels. It is applicants opinion that if those of average skill in the art would have found it obvious that, or would have anticipated that the combination of a soft palate lifter and a tongue retainer in an adjustable universal device for treatment of obstructive sleep apnea in the manner specified in 10/593,172 would be as effective as the testing indicates, the marketplace would be flooded with such devices and numerous examples of similar devices would be evident in the prior art.

It should be noted that the physician who administered the sleep tests, Dr. Barry Levy, a Diplomate of the American Board of Dental Sleep Medicine, recommended the continued use of the subject device over all other devices available.

Applicant respectfully requests that examiner, in light of the above information, re-consider and reverse the rejection of all claims, as amended, and consider the application 10/593,172 to be in condition for allowance.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



Harold E. Cutler

Date: 6/10/10